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10/018,311	04/19/2002	Toshio Miyata	2605/101	1616

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,311	MIYATA, TOSHIO	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *7 and 12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3/12/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-20 are pending in the instant application.

Election/Restrictions

2. Applicant's election with traverse of Group I (claims 1-6 and 8-11) in the Paper filed Nov. 19, 2003 is acknowledged. The traversal is on the ground(s) that since the present application was filed in the United States from a PCT application under 35 USC § 371, the USPTO must apply "unity of invention" standards, and not U.S. restriction standards to the invention. Applicant further argues that the International Preliminary Examination Report found unity of invention, and the Examiner has not presented sufficient reason to overturn the finding of the International Examining Authority, and asserts that the claims share the same or corresponding special technical feature, i.e., features that distinguish the invention from the prior art. This is not found persuasive because, there is prior art over the first group, and therefore there is no unity of invention. The requirement is still deemed proper and is therefore made FINAL.

Claims 7 and 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-6 and 8-11 are currently under examination.

Claim Objections

3.1 Claim 5 is objected to because of the following informalities: the word "these" on the second line should be replace with "this" to be grammatically correct. Appropriate correction is required.

3.2 Claim 10 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. For unacceptable multiple dependent claim wording, see MPEP § 608.01(n) *B*. 3., for an example showing reference to two sets of claims to different features.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 1-6 and 8-11 are directed to the protein of SEQ ID NO: 2, identified as MEG-3 protein, and nucleic acid encoding the protein of SEQ ID NO: 2, vector, transformed cells and recombinant method of producing protein. The instant specification discloses that MEG-3 is a 733 amino acid protein, and asserts that it is a cytoplasmic protein involved in signal transduction, member of the tumor necrosis factor family of receptors. However,

the protein or encoding DNA do not have any specific and substantial utility, or a well established utility, as determined according to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The specification teaches that the proteins and nucleic acids can be used in methods such as screening assays to identify related proteins, to raise monoclonal or polyclonal antibodies, use of the nucleic acid to make proteins, making transgenic or knockout animals to use as animal model systems to determine the effects of Meg-3 or to screen for pharmaceuticals, expressing the nucleic acid in order to make the protein, or to determine tissue expression by Northern blotting, for example.

However, none of these uses are considered to be specific or substantial utilities for either the protein or the encoding nucleic acid molecules. Methods such as identification of homologous genes, use to recombinantly produce protein or use to generate antibodies are considered general methods applicable to any protein and/or nucleic acid, and are not considered specific or substantial. Use of the MEG-3 protein in assays is also not a specific and substantial utility, or making and using transgenic animals is only further research to discover what the activities and biological significance of the protein is.

The instant application teaches that a motif search on the deduced amino acid sequence of the MEG-3 protein of SEQ ID NO: 2 revealed an amino acid sequence that closely resembles many proteins called proline rich proteins, and the region comprising the 81 amino acid residues from amino acid 621 to 701 is especially rich in proline, and possesses in two regions the sequence xPESPPPAxP, which resembles the amino acid sequence xPxxPPPFxP of the proline rich peptide (PR peptide) that binds to the SH3 (Src homology 3 domain). The instant

specification asserts that based on this homology, and the cytoplasmic location of the protein (Fig. 2), suggests the possibility that the C-terminus structure of the Meg-3 protein may bind as a PR domain to the SH3 domain of an intracellular signal transduction molecule and therefore be involved in signal transduction. Although possible that the MEG-3 protein may be involved in a signal transduction pathway, this is not considered a specific or substantial utility, because there is no disclosure of what signal transduction pathway the protein could be involved in, or what other molecules the Meg-3 protein could interact with. There are many different proteins having proline-rich sequences that interact with a number of different proteins that are involved in many different signal transduction pathways. Majidi et al., (The Journal of Biological Chemistry, Vol. 273, June 26, 1998, pages 16608-16614) states in the second column of page 16608:

> Specific proline-rich sequences constitute consensus motifs that serve as binding sites for specific domains in signaling proteins or as substrates for certain protein kinases (5). The recognition site for Src homology 3 (SH3) domains consists of a proline-rich sequence with at least one PXXP core (6-9). SH3 domains are peptides 60-70 amino acids in length involved in protein-protein interactions leading to the activation of a wide variety of signal transduction pathways, including those leading to the activation of the MAP kinase family members ERK1, ERK2, and JNK(10-14). Characterization of the sequence requirements for binding to various SH3 domains has revealed that the amino acids surrounding the PXXP core participate in determining the specificity of these interactions. Ren et al. (8) identified a 10-amino acid proline-rich consensus sequence that mediates association between the c-Abl SH3 domain and a variety of interacting proteins. Since then, a number of SH3 binding proteins have been identified, including mSos, PI3K, p22phox, AAP1, RIN1, and FBPWW (15-19).

Alejandro et al. (Journal of Bacteriology, Vol. 185, No. 14, pages 4081-4086) states in the first column on page 4081:

> The Src homology domain 3 (SH3) is a ubiquitous small protein domain that typically spans about 55 to 70 residues and is found as a modular entity in a variety of eukaryotic and viral proteins (9, 31). The SH3 domain was originally discovered as a homologous module through sequence comparisons of several tyrosine kinases. It has been demonstrated that SH3 domains participate in a number of signal transduction mechanisms and cell-cell communication by binding to poly-proline-rich peptides that are folded in a left-handed poly-proline helix II (PPII) conformation, with the consensus general form P-X-X-P, where P is proline and X is any amino acid (8, 9, 31). Recognition of the target motif mediates protein-protein interactions by forming and maintaining macromolecular aggregates either inter- or intramolecularly.

Therefore, identification of proline-rich regions in the MEG-3 protein does not confer an immediate specific and substantial utility for the protein, since many different proteins have this motif and are involved in different signal transduction pathways. "Involvement in a signal transduction pathway" is not in and of itself a specific and substantial utility, and additionally there is no evidence besides the proline-rich motif and cytoplasmic location that indicates that the Meg-3 protein is involved in any signal transduction pathway.

The instant application also asserts that because the MEG-3 transcript in kidney tissue is specifically restricted to the mesangial cell, oligonucleotides of the present invention are useful as probes and primers that enable specific detection of the mesangial cell, and since the mesangial cell is closely related to the function of the glomerulus, the oligonucleotides of the invention may serve as a useful tool in pathological analysis of the kidney. Additionally, the specification asserts that antisense nucleic acid of the invention is an important tool for demonstrating the role of Meg-3 in the mesangial cells, and also useful for regulating diseased conditions caused by increased expression of Meg-3. However, these are not specific and

substantial utilities, since other genes expressed specifically in mesangial cells can be used for the purpose of detection. Also, use of a molecule to determine the role of that molecule is not a specific and substantial utility. The instant application also teaches that associated antibodies can be used either diagnostically to detect abnormal levels of the Meg-3 protein, and identify disorders or diseases, or prophylacticly or therapeutically to treat diseases or disorders associated with increased expression of Meg-3. However, there is no nexus between any of the diseases or disorders and the molecules of the instant invention. Given no disease state or any other function or activity known for the protein, the protein is not considered to have utility. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a protein which has undetermined function or biological significance, and the use of a protein to discover its properties does not constitute a specific, substantial utility. All of the biological activities of a protein need not be known to obtain a patent, but there must be some specific and substantial activity or function known. It is possible that after further characterization, this protein might be found to have a patentable utility, such as association with a specific disease. This further characterization, however, is part of the act of invention, and

until it has been undertaken the Applicants' claimed invention is incomplete. Because there is no specific and substantial utility asserted, credibility cannot be assessed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5.1 Claims 1-6 and 8-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Even if the specification were enabling of how to use the Meg-3 polypeptide (or nucleic acid), enablement would not be found commensurate in scope with the claims. If one of skill in the art does not know how to use the nucleic acids or proteins of the instant invention, the skilled artisan would clearly not know how to use nucleic acid molecules or encoded proteins that are substantially different from those disclosed.

5.2 Claims 1, 3, 5 and 8-10 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a polypeptide sequence consisting of SEQ ID NO: 2. However, the claims as written include polypeptides comprising fragments and homologues, encompass polypeptides that vary substantially in length and also in amino acid composition. The instant disclosure of a single polypeptide, that of SEQ ID NO: 2 with no disclosed specific activities, does not adequately

support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated polypeptide sequence SEQ ID NO: 2. Receptor function, however, cannot be reliably predicted

from protein sequence homology. For example, Transforming Growth Factor (TGF-beta) Family OP-1 induces metanephrogenesis whereas closely related TGF-beta family members-BMP-2 and TGF-beta1-have no effect on metanephrogenesis under identical conditions (Vukicevic et al., 1996, PNAS USA 93:9021-9026). Platelet-derived Growth Factor (PDGF) Family VEGF, a member of the PDGF family, is mitogenic for vascular endothelial cells but not for vascular smooth muscle cells while PDGF is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (Tischer et al., U.S. Patent 5,194,596, column 2, line 46 to column 3, line 2). Finally, vertebrate growth hormone of 198 amino acids becomes an antagonist (inhibitor of growth) when a single amino acid is changed (Kopchick et al, U.S. Patent No. 5,350,836). Even 99% homology does not allow predictability in this instance. Given the unpredictability of homology comparisons, and the fact that the specification fails to provide objective evidence that the additional sequences are indeed species of the claimed genus it cannot be established that a representative number of species have been disclosed to support the genus claim. No specific activity is set forth for the additional sequences. The instantly claimed genus is not so limited and the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polynucleotides or proteins encompassed.

5.3 Claims 5 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA encoding the protein of claim 1, in which the DNA hybridizes with the ***complement*** of the nucleotide sequence of SEQ ID NO: 1, does not reasonably provide enablement for a DNA encoding the protein of claim 1, in which the DNA hybridizes with the nucleotide sequence of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make and use the invention commensurate in scope with these claims. The nucleic acid sequence of SEQ ID NO: 1 encodes the protein of SEQ ID NO: 2. However, a nucleic acid sequence that would hybridize to the nucleic acid sequence of SEQ ID NO: 1 would be the complement of SEQ ID NO: 1, and would not encode the same protein, and the specification has not taught how to use a protein encoded by the complement of SEQ ID NO: 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6.1 Claims 1-6 and 8-11 are vague and indefinite because claim 1 encompasses a protein comprising the amino acid sequence in which one or more amino acids are replaced, deleted, added, and/or inserted, and being functionally equivalent to the protein comprising the amino acid sequence of SEQ ID NO: 2, and there is no upper limit placed on the number of amino acid changes that may be made. It is not clear at what point the claimed protein would be a different protein from that of SEQ ID NO: 2. Although the claim has the limitation of being "functionally equivalent", there is no definition of what activities a protein that is "functionally equivalent" would have, and the specification of page 7, line 17 to page 18, line 12 does not provide a specific activity for the protein.

6.2 Claims 5 and 8-10 are also vague and indefinite, because claim 5 encompasses a DNA molecule which hybridizes under "**stringent**" conditions to the nucleotide sequence of SEQ IDN

NO: 1. Though the specification on pages 8-9 describes various hybridization and wash conditions, they are exemplary. The term **"stringent"** is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

6.3 Claims 6 and 11 are also indefinite, because claim 6 encompasses a DNA hybridizing "specifically" with the DNA of claim 4, and the specification does not define the what the term "hybridizing specifically" means, and the claims therefore do not clearly set forth the metes and bounds of the patent protection desired.

Priority Determination

7. Claim for foreign priority.

37 CFR 1.55 states that:

> (a) An applicant in a nonprovisional application may claim the benefit of the filing date of one or more prior foreign applications under the conditions specified in 35 U.S.C. 119(a) through (d) and (f), 172, and 365(a) and (b).

Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 119 from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention. Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons given above and it claims priority to JAPAN 11/123561, the prior application does not meet those requirements and, therefore, is unavailable under 35 U.S.C. § 119. The effective priority date of the instant application is considered to be the filing date of PCT application PCT/JP00/02831, April 28, 2000, because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8.1 Claims 1, 3, 5, 6, 8, 9 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Ottenwaelder et al., Database PIR_76, Accession No. T46394, Feb. 4, 2000, Database GenEmbl nucleotide sequence Accession No. AL137555.

Claims 1, 3, 5, 6, 8, 9 and 11 encompass a protein comprising the amino acid sequence in which one or more amino acids are replaced, deleted, added, and/or inserted, and being functionally equivalent to the protein comprising the amino acid sequence of SEQ ID NO:2, DNA encoding the protein, vector and transformant comprising the DNA, and DNA hybridizing specifically with the DNA of SEQ ID NO: 1 and having a chain length of at least 15 nucleotides.

Ottenwaelder et al. disclose a cDNA clone encoding a hypothetical protein encoded by mRNA from adult testis clone DKFZp434H0820, that is 94.6% identical to the protein of SEQ ID NO: 2 of the instant invention, and is 99.9% identical to amino acids 38-733 of the instant invention with one mismatch at amino acid 305. The instant application on page 7, line 17 to page 18, line 12, defines "functionally equivalent" as having biological properties that are the same as Meg-3, and gives as examples the possibility of playing a part in signal transduction, or

being expressed in specific cells. Since the protein of Ottenwaelder et al. is identical to the protein of SEQ ID NO: 2 except for a small N-terminal truncation and one amino acid difference, the protein of Ottenwaelder et al. is likely an allelic variant, and would be expected to have the same activities as the protein of the instant application. For instance, a biological property of the protein of the instant invention would be the generation of antibodies that would bind to it, and given 99.9% homology over most of the protein, the majority of antibodies that bind the protein of SEQ ID NO: 2 would also bind the protein of Ottenwaelder et al. The cDNA of Ottenwaelder et al. is 94.3 identical to the nucleotide sequence of SEQ ID NO: 1, and 99.95% identical to nucleotides 163-2251 of SEQ ID NO: 1 (one mismatch in the open reading frame). This nucleic acid molecule would therefore specifically hybridize to SEQ ID NO: 1. Since the cDNA of Ottenwaelder et al. is cloned, it is in a vector and transformed cell.

8.2 Claims 1, 3, 5, 6 and 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al., United States Published Application No. 20020091244, priority date Dec. 31, 1997 from parent application 09/002,485.

Claims 1, 3, 5 and 6-11 encompass a protein comprising the amino acid sequence in which one or more amino acids are replaced, deleted, added, and/or inserted, and being functionally equivalent to the protein comprising the amino acid sequence of SEQ ID NO: 2, DNA encoding the protein, vector and transformant comprising the DNA, and DNA hybridizing specifically with the DNA of SEQ ID NO: 1 and having a chain length of at least 15 nucleotides, and method of producing the protein.

Lal et al. disclose a protein (SEQ ID NO: 39) that is identical to amino acids 556-578 of SEQ ID NO: 2, encoded by a nucleic acid molecule (SEQ ID NO: 116) that is 99.8% identical to

nucleotides 1682-2227 of SEQ ID NO: 1 of the instant invention. Since the instant specification does not specifically define what a "functionally equivalent" protein would be, the protein of Lal et al. could generate antibodies that would bind to the protein of SEQ ID NO: 2 of the instant invention, and the DNA of Lal et al. would also hybridize under stringent conditions to the nucleic acid of SEQ ID NO; 1 of the instant invention. Lal et al. also teach vector, host cell, and recombinant method of producing protein (claims 4-6). Therefore, Lal et al. anticipates the claims.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Eileen B. O'Hara

Patent Examiner